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21186	7590	01/28/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			FORMAN, BETTY J	
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1634

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/038,284	<b>Applicant(s)</b> EHRICHT ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 25-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 28 October 2003 in which claims 1-19 were amended; claims 25-43 were added; the specification, pages 6 and 10 were amended and Fig. 2 was amended. All of the amendments have been thoroughly reviewed and entered.

The previous objects and rejections in the Office Action dated 4 August 2003, not reiterated below are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the amended claims. New grounds for rejection necessitated by amendment are discussed.

Claims 1-19 and 25-43 are under prosecution.

### ***Information Disclosure Statement***

2. Applicant's request for consideration of German Application No. 199 40 750.A1 is acknowledged. As noted on the 1449, the English language abstract for German Application No. 199 40 750.A1 has been considered by the examiner. Therefore, the German Application No. 199 40 750.A1 has been considered to the extent that the information provided in the abstract has been considered. As further noted on the 1449, German Application No. 199 40 750.A1 is a non-English language document. Because the examiner does not read and/or understand German and because Applicant has not provided an English language translation of the German document, the complete text of the German document has not been read by the

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examiner. However, as stated above, the German Application No. 199 40 750.A1 has been considered to the extent that the information provided in the abstract has been considered.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 31, 33, 35, 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitations “micro-structured heating element include nickel-chromium thin film resistive heaters”; “chamber body further includes an additional sealing surface adapted to releasably connect to the chamber support”; protein probes including “antibodies, receptor molecules, hormones and pharmaceutically active peptides”; detection methods of “transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry”; and “capillary gap adapted to provide almost simultaneous performance of a chip-based characterization and at least one reprocessing reactions and conditioning reactions” have been added to the newly added claims 31, 33, 35 and 38-40.

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However, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 8-10, 12-15, 17-19, 25-36 and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 1, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area having an optically permeable zone of detection (i.e. transparent window, Column 19, lines 20-29) adapted to immobilize nucleic acids, peptides or proteins e.g. polymerase enzymes (Column 8, lines 23-42) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar

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glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein the gap (chamber) is provided with amplification and characterization means i.e. temperature control means for thermocycling and pcr amplification whereby nucleic acids are amplified and characterized via amplification (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Regarding Claim 2, Lipshutz et al disclose the device comprising temperature adjustment means connected to the chamber support and permit rapid temperature control of the gap i.e. provide conditions for PCR amplifications within the chamber (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Regarding Claim 3, Lipshutz et al disclose the device wherein the temperature adjustment means are situated on the side of the chamber support facing the chamber body (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 4, Lipshutz et al disclose the device wherein the optically permeable zone of detection includes detection spots (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29) and wherein the temperature adjustment means are configured such that the optical transparency of the chip remains unaffected i.e. the "heater insert" is disposed on the side of the chamber thereby not affecting the transparency of the chip Fig 2B #106/112 (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 5, Lipshutz et al disclose the device wherein the temperature adjustment means comprises micro-structured heating elements i.e. nickel-chromium film (Column 24, lines 53-59) and micro-structured temperature sensors (Column 25, lines 7-41).

Regarding Claim 8, Lipshutz et al disclose the device wherein the chamber support and body consist of glass, synthetic material or optically permeable synthetic materials e.g. nylon,

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Teflon, topaz, polycarbonate, polystyrene, PMMA and/or polymethane, ethyl acrylate (Column 15, lines 26-58).

Regarding Claim 9, Lipshutz et al disclose the device wherein the chamber support consists of thermally conducting material i.e. the heating/cooling means are embedded within the support which then conducts the heat to the reaction chamber (Column 27, lines 37-47 and Fig. 8 #806).

Regarding Claim 10, Lipshutz et al disclose the device wherein the chip consists of optically permeable materials e.g. glass (Column 15, lines 25-29).

Regarding Claim 12, Lipshutz et al disclose the device further comprising an inlet and an outlet spatially separate from each other i.e. fluid channel #212 is an inlet for reaction chamber #214 and fluid channel #216 is an outlet for reaction chamber #214 (Fig. 3 and Column 16, lines 12-18).

Regarding Claim 13, Lipshutz et al disclose the device wherein the inlet and outlet are arranged unilaterally and are separated by a gas reservoir nose i.e. gas permeable membrane to allow escape of accumulated gas (Column 17, lines 28-38)

Regarding Claim 14, Lipshutz et al disclose the device wherein the chamber body is sealingly and unreleasably connected with the chamber support with an adhesive or welding connection (Column 15, lines 20-29)

Regarding Claim 15, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which nuclei acid probes are immobilized i.e. positionally distinct probes (Column 9, lines 30-35 and Column 9, lines 20-29).

Regarding Claim 17, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which probes in the form of peptides or proteins are immobilized e.g. polymerase enzymes (Column 8, lines 23-42).

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Regarding Claim 18, Lipshutz et al disclose the device wherein the capillary gap is adapted to allow characterization by optical detection (i.e. transparent window for observation of a “particular analysis”, Column 19, lines 20-29)

Regarding Claim 19, Lipshutz et al disclose the device is adapted to allow characterization (i.e. transparent window for observation of a “particular analysis”, Column 19, lines 20-29). The instantly recited “by a silver precipitation reaction” does not describe or define a structural component of the device. Lipshutz et al teach the device is adapted for characterization via observation through a transparent window, and because the recitation “by a silver precipitation reaction” does not describe or define additional structural components of the device, the device of Lipshutz et al is encompassed by the instantly claimed device.

### **Response to Arguments**

7. Applicant argues that Lipshutz teaches a plurality of reaction chambers and therefore does not teach the instantly claimed device comprising a single chamber. The argument has been considered but is not found persuasive because the open claim language “comprising” encompasses any additional elements taught by Lipshutz. The device of Lipshutz comprises a chamber comprising a chamber body and optically permeable support sealed together to form a capillary gap (i.e. well or cavity space forming the reaction chamber between the body and support, Column 15, lines 14-17) whereby the gap forms a single reaction chamber. Therefore, Lipshutz teaches the device as claimed.

Applicant further argues that Lipshutz does not teach a capillary gap adapted to amplify and characterize nucleic acids as claimed. The argument has been considered but is not found persuasive because as cited above, Lipshutz specifically teaches the gap (chamber) is provided with amplification and characterization means i.e. temperature control means for thermocycling and pcr amplification whereby nucleic acids are amplified and characterized via amplification (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).



**NEW CLAIMS**

Regarding Claim 25, Lipshutz et al disclose a device for duplication and characterizing nucleic acids comprising a chamber support, a chamber body on the support and a capillary gap intermediate the support and body, the gap being adapted to act as a single chamber for both the reaction (e.g. hybridization) and characterization (detection) of nucleic acids (e.g. Fig. 7A; Column 15, lines 9-34; and Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Lipshutz et al teach their device comprises the chamber, support and gap whereby a single chamber is formed for reaction and characterization of nucleic acids. They further teach their device comprises additional reaction chambers. However, a single chamber is formed for hybridization and detection of nucleic acids. Therefore, the device of Lipshutz et al is encompassed by the instant claim.

Regarding Claim 26, Lipshutz et al disclose their device wherein the chamber includes an optically permeable chip (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 27, Lipshutz et al disclose their detection area includes immobilized probes (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 28, Lipshutz et al disclose their immobilized probes include nucleic acids, peptides or proteins (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 29, Lipshutz et al disclose the device wherein the detection area is optically permeable (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 30, Lipshutz et al disclose the device wherein the capillary gap is temperature adjustable and flow controllable. The claim does not require that the device comprise means for temperature adjustment or flow control of the capillary gap. The claim

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merely requires that the capillary gap be adjustable and controllable. Lipshutz et al teach the temperature and flow within the gap is controlled (Column 27, line 37-Column 29, line 67). Therefore, Lipshutz et al teach the device as claimed.

Regarding Claim 31, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 32, Lipshutz et al disclose the device of Claim 1 wherein the temperature adjustment means includes micorstructured sensors (Column 25, lines 7-10).

Regarding Claim 33, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 34, Lipshutz et al disclose the device of Claim 1 wherein at least one of the chamber support and the chamber body include an optically permeable synthetic materials selected from the group consisting of nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and polymethane ethyl acrylate (Column 15, line 49-Column 16, line 2).

Regarding Claim 35, Lipshutz et al disclose the device of Claim 1 wherein the chamber includes additional sealing surface adapted to releasable connect to the support (e.g. Column 4, lines 55-58; Column 7, lines 65-67; Column 16, lines 42-45; and Column 23, lines 1-27).

Regarding Claim 36, Lipshutz et al disclose the device of Claim 1 wherein the nucleic acid molecules include DNA or RNA (Column 9, line 30-Column 11, line 57).

Regarding Claim 39, Lipshutz et al disclose the device of Claim 18 wherein the optical detection includes at least one of transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry (Column 12, line 63-Column 13, line 9).

Regarding Claim 40, Lipshutz et al disclose the device of Claim 1 wherein the capillary gap is adapted to provide almost simultaneous performance of characterization and reprocessing or conditioning (i.e. transparent window, Column 19, lines 20-29). The claimed "adapted to provide almost simultaneous performance...." does not define or describe

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structural components of the device. The transparent window of Lipshutz et al would provide for simultaneous observation and hybridization. However, because the claim recitation does not describe structural limitations of the device, the transparent window of Lipshutz is encompassed by the instantly claimed device.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claims 41-43, Lipshutz et al disclose the device wherein various reactions are performed within a chamber e.g. pcr, transcription (Column 4, lines 1-45). The instantly claimed functions of the device i.e. pcr, reverse transcription, digestive process do not define or describe structural components of the device and therefore do not further limit the claimed device.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of McBride et al (U.S. Patent No. (6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 6 and 7, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein electro-osmotic flow is provided via electrodes (Column 28, lines 56-67) but they do not teach the a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the

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electrodes of Lipshutz et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

### **Response to Arguments**

10. Applicant argues that McBride does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Atwood et al (U.S. Patent No. 5,475,610, filed 20 April 1992).

Regarding Claim 11, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein one zone of the chip is a reaction chamber for PCR (Column 19, lines 1-19) but they do not teach the reaction chamber comprises a conical recess. However, it was well known in the art at the time the claimed invention was made that the preferred surface for PCR reactions comprise conical recesses as taught by Atwood et al (Column 12, lines 28-47). Atwood et al further teach that conical recesses provide very tight temperature control for all

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samples and within each sample throughout the PCR cycles (Column 12, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the conical recess of Atwood et al to the PCR reaction chamber of Lipshutz et al thereby providing means for very tight temperature control for the expected benefit of controlling temperature of each sample throughout the PCR cycles as taught by Atwood et al (Column 12, lines 40-47).

### **Response to Arguments**

12. Applicant argues that Atwood does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

13. Claim 16, 17 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claims 16 and 37, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area and being optically permeable at least at the detection area (i.e. transparent window, Column 19, lines 20-29) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is

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manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein the detection area is configured in the form of spots onto which nuclei acid probes are immobilized i.e. positionally distinct probes constructed using techniques known in the art (e.g. Fodor et al, Column 9, lines 30-35 and Column 9, lines 20-29). But Lipshutz et al do not specifically teach the probe are immobilized through spacers. However, Fodor et al do teach their probes are immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Lipshutz et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Regarding Claim 17, Lipshutz et al teach the device wherein proteins are immobilized (Column 8, lines 39-42) but they do not teach the detection area comprises probes in the form of spots. However, detection areas (arrays) comprising spots of protein probes were well known in the art at the time the claimed invention was made as taught by Fodor et al who teach the peptide array provide a tool for high-density peptide-specific antibody recognition (Column 8, line 61-Column 9, line 30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the peptide probes of Fodor et al to the detection area of Lipshutz et al to thereby provide for high-density antibody screening for the expected benefits of determining relative binding affinity between a plurality of peptides simultaneously as taught by Fodor et al (Column 2, lines 44-49).

Regarding Claim 38, Lipshutz et al teach the device wherein the proteins included receptor molecules e.g. antibodies (Column 8, lines 36-42).

**Response to Arguments**

14. Applicant argues that Fodor does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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**Conclusion**

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741 until 13 January 2004. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0507.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
January 22, 2004